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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,635	10/12/2000	Olli Kallioniemi	4239-55278	8528

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/622,635	KALLIONIEMI ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-9,12,14,16-18,20,22,24-42,46-63,66-78,86-89,91,92,98-100 and 116-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-9,12,14,16-18,20,22,24-42,46-63,66-78,86-89,91,92,98-100 and 116-118.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 September 2006 has been entered.

Status of the Claims

2. This action is in response to papers filed 8 September 2006 in which claims 1, 16, 32, 53, 88 were amended and claims 11, 19, 114-115, 119-123 were canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 20 April 2006 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims1-2 4-9 12 14 16-18 20 22 24-42 46-63 66-78 86-89 91-92 98-100 116-118 are under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2, 4-9, 12, 14, 16-18, 20, 22, 29-30, 46-49, 53-61, 70, 87-89, 91-92 and 98-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enghardt et al (Journal of Histotechnology, 1995, 18(1): 51-55) in view of Hozier (U.S. Patent No. 5,326,691, issued 5 July 1994) and/or Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998).

Regarding Claim 1, Enghardt et al disclose a method of parallel analysis of biological specimens comprising obtaining a plurality of donor specimens, placing each donor specimen in an assigned location in a recipient array (cassette, and page 55, second full paragraph), obtaining a plurality of copies of the recipient array such that the copies maintain their assigned locations (page 53, right column "slides"), performing analysis of each copy and comparing the results of the analysis i.e. immunostained and analyzed (page 53, last paragraph-page 54, left column). Enghardt et al further teach the method compares first array to a second array wherein using different assays i.e. the slides are stained with the antibodies so as to illustrate individual binding to tissues (Fig. 3) and the arrays are assayed for antibody staining to the test array to identify prognostic target for disease and/or presence of protein i.e. melanoma-antibody HMB-45 (Fig. 3).

Enghardt et al teach the method wherein the analysis is immunological analysis (page 54, left column and page 52, Table 1) but they are silent regarding a second hybridization assay. However, Hozier teach a method similar to that of Enghardt et al comprising placing a specimen in an assigned location to form an array (Column 12, line 52-Column 13, line 53), obtaining a plurality of copies of the array (Column 14, lines 8-52) and subjecting the arrays to various assays (Abstract and Column 8, lines 36-41). Furthermore, Fodor et al teach a motivation to perform both immunoassays and hybridizations on the samples i.e. allows simultaneous analysis of and correlation of structural features and gene expression (Column 78, line 60-Column 79, line 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the analysis of Enghardt et al by performing both immunoanalysis and nucleic acid hybridization on the arrayed samples. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Hozier and further for the expected benefit of providing simultaneous analysis and correlation of structural features and gene expression as desired in the art (Fodor et al, Column 78, line 60-Column 79, line 5).

Regarding Claim 2, Enghardt et al disclose the method wherein the donor specimen is obtaining by boring (i.e. punched) an elongated sample from the specimen (page 53, paragraph spanning left to right column).

Regarding Claim 4, Enghardt et al disclose the method wherein the donor specimen is from a population of cells i.e. tumor tissue (Fig. 3).

Regarding Claim 5, Enghardt et al disclose the method wherein the donor specimen is from a cytological preparation i.e. tumor cells (Fig. 3).

Regarding Claim 6, Enghardt et al disclose the method wherein placing the donor specimen in an assigned location comprises forming an elongated receptacle in a donor block (page 52, right column), obtaining an elongated specimen (page 53, right column) and obtaining a plurality of copies by sectioning the array transverse to the donor specimen (page 53, right column, "slides" and Fig. 2).

Regarding Claim 7, Enghardt et al disclose the method wherein the donor specimen is placed in a receptacle having a size and shape "complementary" to the size and shape of the specimen (page 52, right column and page 53, right column).

Regarding Claim 8, Enghardt et al disclose the method wherein forming the elongated receptacle comprises forming a cylindrical bore in the recipient block and the donor specimen is obtained by boring a cylindrical tissue specimen from the donor block wherein the diameters of the receptacle and donor are substantially the same (pages 52-53).

Regarding Claim 9, Enghardt et al disclose the method further comprising associating a clinical characteristic with each assigned location i.e. diagnosis (page 55, first paragraph).

Regarding Claim 12, Enghardt et al disclose the method further comprising determining whether there are correlations between clinical characteristics associated with each location (page 55, left column).

Regarding Claim 14, Enghardt et al disclose the method wherein clinical characteristics are determined apart from array analysis and the characteristics are tumor grade, size or status i.e. diagnosis (page 55, first paragraph).

Regarding Claim 16, Enghardt et al disclose a method of parallel analysis of biological specimens comprising forming a donor block comprising a biological specimen embedded in embedding medium (page 51, right column and page 53) obtaining a plurality of donor specimens cores (page 53), boring recipient cores from recipient embedding medium form an array of elongated receptacles (page 52, right column) placing each donor cores in the elongated receptacles at assigned locations (page 53) seconding the recipient embedding medium transverse to the elongated receptacles (page 53 "slides") performing different biological analysis on each cross-section and comparing the results to determine correlations (page 53, last paragraph-page 54, left column). Enghardt et al further teach the method compares first array to a second array wherein using different assays i.e. the slides are stained with the antibodies so as to illustrate individual binding to tissues (Fig. 3) and the arrays are assayed for antibody staining to the test array to identify prognostic target for disease and/or presence of protein i.e. melanoma-antibody HMB-45 (Fig. 3).

Enghardt et al teach the method wherein the analysis is immunological analysis (page 54, left column and page 52, Table 1) but they are silent regarding a second hybridization assay. However, Hozier teach a method similar to that of Enghardt et al comprising placing a specimen in an assigned location to form an array (Column 12, line 52-Column 13, line 53), obtaining a plurality of copies of the array (Column 14, lines 8-52) and subjecting the arrays to

various assays (Abstract and Column 8, lines 36-41). Furthermore, Fodor et al teach a motivation to perform both immunoassays and hybridizations on the samples i.e. allows simultaneous analysis of and correlation of structural features and gene expression (Column 78, line 60-Column 79, line 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the analysis of Enghardt et al by performing both immunoanalysis and nucleic acid hybridization on the arrayed samples. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Hozier and further for the expected benefit of providing simultaneous analysis and correlation of structural features and gene expression as desired in the art (Fodor et al, Column 78, line 60-Column 79, line 5).

Regarding Claim 17, Enghardt et al disclose the method further comprising comparing the results to clinical information about the specimen (page 54, left column and Fig. 3).

Regarding Claim 18, Enghardt et al disclose the method wherein the specimen is from a tumor (Fig.3).

Regarding Claim 20, Enghardt et al disclose the method further comprising comparing the results to clinical information about the subject from whom the specimen was obtained (page 55, left column and Fig. 3).

Regarding Claims 22 and 98-100, Enghardt et al disclose the method wherein the donor core is substantially cylindrical and has a diameter of "about" 1mm(page 53). Enghardt et al do not teach a diameter of less than 1mm (or 0.3 to 2.0) and a length of 1 to 4 mm. However, the courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed

device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Therefore, the instantly claimed dimensions would have been an obvious variation of the dimensions of Enghardt et al.

Regarding Claim 29-30, Enghardt et al disclose the method wherein the comparing comprises determination of protein expression by immunological analysis (Table 1 and page 53-54).

Regarding Claim 46-48, Enghardt et al teach the method wherein analysis specifically includes reagent analysis, quality control and analysis of differentiation (page 55, left column). They do not teach the intended uses recited in Claims 45-48. However, one of ordinary skill in the art would have been motivated to apply the method of Enghardt et al for claimed uses based on tissue being examined and anticipated diagnosis.

Regarding Claim 49, Enghardt et al disclose the method wherein donor specimens are from one or more tumors (Fig.3).

Regarding Claim 53, Enghardt et al disclose a method of analyzing cellular specimens in a matrix with specimens positioned at predetermined known locations such that multiple copies of the matrix are provided in a two dimensional array, the method comprising exposing sequential copies of the matrix to an agent which interacts with the specimens to identify specimens which share a biological property i.e. antibody binding (pages 53-54). Enghardt et al further teach the method compares first array to a second array wherein using different assays i.e. the slides are stained with the antibodies so as to illustrate individual binding to tissues (Fig. 3) and the arrays are assayed for antibody staining to the test array to identify prognostic target for disease and/or presence of protein i.e. melanoma-antibody HMB-45 (Fig. 3).

Enghardt et al teach the method wherein the analysis is immunological analysis (page 54, left column and page 52, Table 1) but they are silent regarding a second hybridization assay. However, Hozier teach a method similar to that of Enghardt et al comprising placing a

specimen in an assigned location to form an array (Column 12, line 52-Column 13, line 53), obtaining a plurality of copies of the array (Column 14, lines 8-52) and subjecting the arrays to various assays (Abstract and Column 8, lines 36-41). Furthermore, Fodor et al teach a motivation to perform both immunoassays and hybridizations on the samples i.e. allows simultaneous analysis of and correlation of structural features and gene expression (Column 78, line 60-Column 79, line 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the analysis of Enghardt et al by performing both immunoanalysis and nucleic acid hybridization on the arrayed samples. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Hozier and further for the expected benefit of providing simultaneous analysis and correlation of structural features and gene expression as desired in the art (Fodor et al, Column 78, line 60-Column 79, line 5).

Regarding Claim 54, Enghardt et al disclose the method wherein the specimens are provided in an elongated form and multiple copies are made by sectioning from a three dimensional array such that sequential section maintain a predetermined relationship (page 52, right column and page 53, right column).

Regarding Claim 55, Enghardt et al disclose the method wherein the shared biological property is a molecular characteristic i.e. antibody binding partner (Table 1 and pages 53-54).

Regarding Claim 56, Enghardt et al disclose the method wherein the shared biological property is presence of a protein (Table 1).

Regarding Claim 57, Enghardt et al disclose the method wherein the property is a specific reaction with an antibody specific for a specimen of interest (Table 1).

Regarding Claim 58, Enghardt et al disclose the method wherein the property is "correlated" with another characteristic of the specimens (Table 1). As stated above, the claim is unclear because "other characteristic" is not defined or described. Additionally, the claim

language "correlated" is very broad and interpreted thusly. As such, the protein expression and antibody binding are two characteristics analyzed by Enghardt that meet the limitations of the claim.

Regarding Claim 59, Enghardt et al disclose the method wherein the property includes clinical information about the subject i.e. diagnosis (page 55, left column).

Regarding Claim 60, Enghardt et al disclose the method wherein clinical information includes tumor grade, size or status i.e. diagnosis (page 55, first paragraph).

Regarding Claim 61, Enghardt et al disclose the method wherein the specimen is a tissue specimen (Fig.3).

Regarding Claim 70, Enghardt et al disclose the method wherein the specimens comprise animal cells i.e. tissue cells (Fig. 3).

Regarding Claim 87, Enghardt et al disclose the method wherein the method does not destroy the morphology of the specimen (page 51, right column).

Regarding Claim 88, Enghardt et al disclose a method of parallel analysis of biological specimens comprising obtaining a plurality of donor specimens, placing each donor specimen in an assigned location in a recipient array (cassette, and page 55, second full paragraph), obtaining a plurality of copies of the recipient array such that the copies maintain their assigned locations (page 53, right column "slides"), performing analysis of each copy and comparing the results of the analysis i.e. immunostained and analyzed (page 53, last paragraph-page 54, left column). Enghardt et al further teach the method compares first array to a second array wherein using different assays i.e. the slides are stained with the antibodies so as to illustrate individual binding to tissues (Fig. 3) and the arrays are assayed for antibody staining to the test array to identify prognostic target for disease and/or presence of protein i.e. melanoma-antibody HMB-45 (Fig. 3).

Regarding Claim 89, Enghardt et al disclose the method of Claim 1 further comprising correlating information concerning the specimen with the analysis wherein the information includes tumor grade, size or status i.e. diagnosis (page 55, first paragraph).

Regarding Claim 91, Enghardt et al disclose the method further comprising obtaining donor specimens from a predetermined morphologically defined region of a tumor (e.g. controls and lymph nodes (page 53, left column and Fig. 3).

Regarding Claim 92, Enghardt et al disclose the method further comprising obtaining donor specimens from a predetermined cell structure (e.g. controls and lymph nodes (page 53, left column and Fig. 3).

5. Claims 32-42 rejected under 35 U.S.C. 103(a) as being unpatentable over An et al (U.S. Patent No. 5,882,864, issued 16 March 1999) in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998).

Regarding Claim 32, An et al disclose the method of analyzing genetic changes and gene expression in a tissue specimen (Abstract) the method comprising screening multiple genes with a nucleic acid array (Column 3, lines 35-48) and screening multiple biological specimens in a specimen array with a nucleic acid probe to detect genes which are abnormally expressed (Column 4, lines 18-67) wherein the results of nucleic acid array screening is used to probe the biological specimens (Column 2, line 56-Column 3, lines 9 and Examples 1-2). An et al are silent regarding a number of nucleic acids in the array. However, arrays of hundreds of different nucleic acids were well known in the art at the time the claimed invention was made as taught by Fodor et al. Fodor et al teaches that screening methods using an array of hundreds of different sequences (Column 7, lines 51-67) wherein the high density array

provides for increased throughput and reproducibility (Column 54, lines 30-45). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the high density array screening of Fodor et al to the screening of An et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing for increased throughput and reproducibility (Column 54, lines 30-45).

Regarding Claims 33-34, An et al disclose the method wherein the screening comprises high throughput genomic technique i.e. oligonucleotide arrays (Column 10, lines 43-45).

Regarding Claim 35, An et al teach the method wherein screening comprises searching database or other biomedical information sources (Column 3, lines 45-49).

Regarding Claim 36, An et al teach the method wherein the screening comprises using a cDNA array (Column 8, lines 7-35).

Regarding Claim 37, An et al disclose the method wherein the screening comprises a DNA is assayed for a genetic marker (Column 7, lines 41-49).

Regarding Claim 38, An et al disclose the method wherein the array comprises loci that undergo differential expression in cancer (Column 7, line 41-Column 8, line 5).

Regarding Claim 39, An et al disclose the method wherein the screening comprises hybridizing nucleic acids associated with a cell with the array and determining which loci indicate differential expression (Column 7, line 41-Column 8, line 5 and Fig. 1-15).

Regarding Claim 40, An et al disclose the method further comprising selecting a target that undergoes differential expression and using the probe to screen the specimens (Column 7, line 41-Column 8, line 5 and Fig. 1-15).

Regarding Claim 41-42, An et al disclose the method wherein the specimen is a tumor specimen (Column 7, lines 41-49).

6. Claims 24-28 and 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enghardt et al (Journal of Histotechnology, 1995, 18(1): 51-55) in view of Hozier (U.S. Patent No. 5,326,691, issued 5 July 1994) and/or Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998) as applied to Claim 1 above and further in view of An et al (U.S. Patent No. 5,882,864, issued 16 March 1999).

Regarding Claims 24-28, Enghardt et al, Hozier and Fodor et al disclose the method of Claim 1 as discussed above, but they do not teach the method array comprises an arrangement of nucleic acids on a matrix. However, An et al disclose a similar method of analyzing genetic changes and gene expression in a tissue specimen (Abstract) the method comprising screening multiple genes with a nucleic acid array to identify a biomarker (Column 3, lines 35-48) wherein the array is an oligonucleotide array (Column 10, lines 43-45), the biomarker is selected by genetic analysis (Column 3, lines 31-49) wherein the marker is a marker for gene expression and /or altered gene or its function (Column 7, line 41-Column 8, line 6) and wherein the arrayed markers facilitate diagnosis and treatment (Column 3, lines 1-9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the marker identification of An et al to the tumor analysis method of Enghardt et al for the expected benefit of facilitating diagnosis and treatment of tumors as taught by An et al (Column 3, lines 1-9).

Regarding Claim 116-118, An et al teach the similar method wherein the probes are for an Oncogene (Column 7, line 41-Column 8, line 7) and wherein the tissues are of different stages (progression) and the assays are performed to determine expression (Column 64, lines 28-43)

7. Claims 31, 50-52, 62-63, 68-69, 71-78 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enghardt et al (Journal of Histotechnology, 1995, 18(1): 51-55) in

view of Hozier (U.S. Patent No. 5,326,691, issued 5 July 1994) and/or Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998) as applied to Claim 1 above and further in view of Stapleton et al (U.S. Patent No. 6,103,192, issued 15 August 2000).

Regarding Claims 31, 50-52 and 86, Enghardt et al teach the method wherein a plurality of different tumor tissues are analyzed but they do not specifically teach breast, bladder or prostate tumors, or from a plurality of tumors of the same type. However, Stapleton et al teach the similar method wherein the specimen is breast and/or from plurality of tumors of the same or different type and wherein the method is applicable to any tissue (Column 6 and Example 5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the tumor specimens of Enghardt and Stapleton by analyzing different specimens of the same tissue e.g. breast, prostate or bladder for the obvious benefits of comparative analysis of normal and patient specimens as taught by Stapleton (Column 6, lines 15-25).

Regarding Claim 62-63, 68-69, 71-78, Stapleton et al teach their method wherein the cellular specimen is a cellular suspension that has been converted into a solid specimen (Column 9, line 61-Column 10, line 14) and wherein the suspension is from a body fluid e.g. malignancy from one or more cell lines and immobilized on a support (Column 11, line 27-Column 12, line 50). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the tissue cells of Enghardt et al with clinically important cell suspensions as taught by Stapleton et al for the obvious benefits of inexpensive, rapid and sensitive diagnosis of clinically important specimens at the nucleic acid level as taught by Stapleton et al (Column 5, lines 1-48). Stapleton further teach the method wherein normal tissues are compared to patient tissues (Column 6, lines 20-25) but they do not specifically teach the normal tissues are from a model organism or at different stages of tumor progression. However, it would have been further obvious to analyze tumors from a model

organism and/or at different stages of progression for the obvious benefits of providing a stage-specific analysis and subsequently providing stage-specific treatment based on the analysis.

8. Claims 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enghardt et al (Journal of Histotechnology, 1995, 18(1): 51-55) in view of Hozier (U.S. Patent No. 5,326,691, issued 5 July 1994) and/or Fodor et al (U.S. Patent No. 5,800,992, issued 1 Sept 1998) as applied to Claim 53 above and further in view of Stapleton et al (U.S. Patent No. 6,103,192, issued 15 August 2000) and An et al (U.S. Patent No. 5,882,864, issued 16 March 1999).

Regarding Claims 66 and 67, Enghardt et al disclose a method of parallel analysis of biological specimens comprising obtaining a plurality of donor specimens, placing each donor specimen in an assigned location in a recipient array (cassette, and page 55, second full paragraph), obtaining a plurality of copies of the recipient array such that the copies maintain their assigned locations (page 53, right column "slides"), performing analysis of each copy and comparing the results of the analysis i.e. immunostained and analyzed (page 53, last paragraph-page 54, left column).

Enghardt et al do not teach using a nucleic acid array to identify a biomarker. However, nucleic acid array identification of biomarkers was well known in the art at the time the claimed invention was made as taught by Stapleton et al (Column 1, lines 20-40).

Stapleton et al teach a similar method of parallel analysis of biological specimens comprising obtaining a plurality of donor specimens, placing each donor specimen in an assigned location in a recipient array (matrix) and performing analysis of the specimens using a nucleic acid microarray (Column 1, lines 20-40) wherein the marker is selected by genetic analysis; wherein the marker is for gene expression and altered gene expression in for various

tumor and diagnostic analysis (Column 6, lines 1-25; Column 16, lines 15-18; and Example 7). Stapleton et al further teach a motivation for using the microarray analysis i.e. minimizes the amount of specimen required for analysis and eliminates the need to extract nucleic acids from the sample (Column 5, lines 1-5 and 33-37).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the nucleic acid microarray analysis of Stapleton et al to the specimen analysis of Enghardt et al for the expected benefits of inexpensive, rapid and sensitive diagnosis of clinically important tumors at the nucleic acid level as taught by Stapleton et al (Column 5, lines 1-48).

Enghardt et al and Stapleton do not teach their screening is used to select a probe for an array. However, An et al teach a similar method of tissue specimen analysis wherein the analysis provides disease-specific probes for diagnosis of tumors and specifically her-2 analysis (Column 2, line 56-Column 3, lines 9 and Claim 2). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe selection and her-2 analysis of An et al to the method of Enghardt et al and Stapleton et al to thereby select the arrayed probes from their screening step for the expected benefit of providing an array of disease-specific probes for diagnosis of tumors as taught by An et al (Column 2, line 56-Column 3, lines 9).

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
December 27, 2006